

REMARKS

The Official Action of May 16, 2005 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claims 1 and 2 have been canceled. Claim 3 has been amended in the manner courteously suggested by the Examiner to remove the basis for the rejection under 35 USC 101. With respect to the rejection of claims 3-5 under 35 USC 112, first paragraph, Applicants submit herewith a Declaration of Biological Culture Deposit signed by their undersigned representative to show that all applicable deposit requirements have been satisfied. Applicants respectfully note that the viability requirements of 37 CFR 1.807 are satisfied by the acceptance of the deposit under the Budapest Treaty (see MPEP Section 2409). By virtue of their deposit of the recited cultures, Applicants have satisfied the provisions of 35 USC 112, first paragraph for all of the claims of record.

Claims 1 and 2 were rejected under 35 USC 102(e) as allegedly being anticipated by Chen et al (US Patent 6,635,467) in light of evidence by JP 2000279163. Claims 1 and 2 have now been canceled whereby this rejection is respectfully believed to be moot.

Claims 1 and 2 were also rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of US 6,635,467. This rejection is also respectfully believed to be moot in view of the cancellation of the subject claims.

Claims 1-5 stand rejected under 35 USC 103(a) as allegedly being anticipated by US 6,635,467 (Chen et al) or, in the alternative, under 35 USC 103(a) as allegedly being unpatentable over US 6,635,467 (Chen et al) in the light of evidence by JP 2000279163. Claims 1-5 also stand rejected under 35 USC 103(a) as allegedly being unpatentable over JP 2000279163 and JP 7274978. Applicants respectfully traverse these rejections.

The rejections are based upon the Examiner's premise that the *Monascus* mutants described in the cited references would have characteristics that are identical to, or only slightly different from, the characteristics of the claimed mutants. Applicants submit herewith a Declaration under 37 CFR 1.132 which shows that this is not the case.

The Declaration shows that, based on the respective colors, amounts of GABA produced and functions of *Monascus purpureus* M011, M022 and M1033, it is clear that strains M022 and M1033 of the claimed invention are physically different from strain M011 disclosed in US 6,635,467, even though they are all mutated from *Monascus purpureus* CCRC 31499. Moreover, US 6,635,467 is characterized by mutating *Monascus purpureus* CCRC 31499 to lower the amount of citrinin in the fermentation product, and JP 2000279163 merely disclosed that the GABA product is a *Monascus* fermentation product. In addition, neither reference disclosed or suggested that the amount of GABA produced by *Monascus* strains can be **increased** by mutation. Therefore, persons having ordinary skill in the art, in light of the teachings of US 6,635,467 and JP 2000279163, could by no means have expected, with even a reasonable expectation of success, that *Monascus purpureus* CCRC 31499 could be

mutated to obtain a mutant having an improved production amount of GABA.

Furthermore, as shown in the declaration, the amounts of GABA produced by strains M022 and M1033 (0.834 mg/ml and 2.07 mg/ml, respectively) in medium c are not only much higher than that produced by the parent strain CCRC 314990 (0.134 mg/ml) in the same medium but are also higher than that produced by strain M011 (0.255 mg/ml) disclosed in US 6,635,467.

In view of the evidence in the Declaration, it is respectfully submitted that the cited references do not set forth even a *prima facie* case of either alleged anticipation or alleged obviousness. With respect to obviousness, Applicants respectfully note that, to establish a *prima facie* case, the USPTO must show, among other things, a reasonable expectation of success (see MPEP Section 706.02(j)). However, as shown by the Declaration, the claimed mutants have characteristics that are different than, and that could not reasonably have been expected from, the cited references. Moreover, it is respectfully submitted that the Examiner's expectation that the characteristics of the respective mutants would be identical or substantially identical further shows that the references do not establish even a reasonable expectation of success.

In view of the above, it is respectfully submitted that all rejections and objections of record have been successfully traversed and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

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